

# Notice of Allowability

Application No.

10/031,158

Applicant(s)

PASTAN ET AL.

Examiner

Art Unit

Stephen L. Rawlings, Ph.D.

1643

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 14 November 2005, 25 August 2005 and 13 May 2005.
2. ☒ The allowed claim(s) is/are 1,3,4,6,10,15-17,20,24-28,34,35,45,46 and 56-68.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

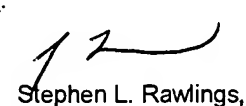
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 20040727; 20050513
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20051201.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☒ Other IDS:20051201.

  
Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1643

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan Alpert Siegel, Ph.D., on December 15, 2005.

2. The application has been amended as follows:

In the claims:

Claims 17, 20, 28, 45, 56, 58, and 65-68 have been amended as follows:

Claim 17. (Currently Amended) A substantially purified recombinant nucleic acid molecule encoding the fusion polypeptide of claim 4.

Claim 20. (Currently Amended) A method for eliciting an immune response in a subject, comprising administering to a subject a composition comprising:

(a) ~~the polypeptide of claim 4~~ a substantially purified polypeptide comprising the amino acid sequence set forth as SEQ ID NO: 14; or

(b) a substantially purified polypeptide consisting of eight to ten consecutive amino acids of the amino acid sequence as set forth as SEQ ID NO: 14, wherein the polypeptide has a leucine or a methionine at the second position and valine or leucine in the last position, and wherein the polypeptide specifically binds HLA-A2;

in a pharmaceutically acceptable carrier, thereby eliciting the immune response in the subject.

Claim 28. (Currently Amended) The method of claim 20, further comprising co-administering to the subject an immune adjuvant selected from the group consisting of a non-specific immune adjuvant, a subcellular microbial product, and a subcellular microbial fraction, a hapten, an immunogenic protein, an immunomodulator, an interferon, a thymic hormone, and a colony stimulating factor.

Claim 45. (Currently Amended) The substantially purified fusion polypeptide of claim 4, wherein the second different polypeptide moiety is selected from the group consisting of a polypeptide tag for isolation, a carrier protein, and a linker.

Claim 56. (Currently Amended) A nucleic acid encoding the fusion polypeptide of claim 4.

Claim 58. (Currently Amended) A method for eliciting an immune response in a subject, comprising administering to a subject a composition comprising the fusion polypeptide of claim 4, thereby eliciting the immune response in the subject.

Claim 65. (Currently Amended) A composition comprising the fusion polypeptide of claim 4 and a pharmaceutically acceptable carrier.

Claim 66. (Currently Amended) The method of claim 20, comprising administering the ~~polypeptide of claim 4~~ substantially purified polypeptide comprising the amino acid sequence set forth as SEQ ID NO: 14.

Claim 67. (Currently Amended) The method of claim 20, comprising administering a the substantially purified polypeptide consisting of at eight to ten consecutive amino acids of the amino acid sequence as set forth as SEQ ID NO: 14, wherein the polypeptide has a leucine or a methionine at the second position and valine or leucine in the last position, and wherein the polypeptide specifically binds HLA-A2.

Claim 68. (Currently Amended) A method for eliciting an immune response in a subject comprising administering to a subject a composition comprising a fusion polypeptide comprising a polypeptide moiety consisting of at eight to ten consecutive amino acids of the amino acid sequence as set forth as SEQ ID NO: 14, wherein the polypeptide has a leucine or a methionine at the second position and valine or leucine in the last position, and wherein the polypeptide specifically binds HLA-A2, and further comprising a second different polypeptide moiety.

### ***Conclusion***

3. Claims 1, 3, 4, 6, 10, 15-17, 20, 24-28, 34, 35, 45, 46, and 56-68 have been allowed.


4. Claims 1, 3, 4, 6, 10, 15-17, 20, 24-28, 34, 35, 45, 46, and 56-68 have been renumbered as claims 1, 6, 11, 2-4, 8, 17, 20-23, 27, 24, 28, 29, 13, 30, 15, 16, 12, 9, 18, 5, 10, 19, 7, 14, 25, 26, and 31, respectively.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1643

slr  
December 16, 2005